FAX COVER SHEET

NORRIS, McLaughlin & Marcus 220 East 42nd Street New York, NY 10017 facsimile (212) 808-0844 telephone (212) 808-0700

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED CENTER

TOTAL PAGES (PLUS COVER SHEET) =13

JAN 1 6 2004

TO

ATTENTION

: Examiner Cynthia Collins

ART UNIT

: 1638 : 703 872 9306 ; 703 746 5032

RÉ

SERIAL NO.

09/831,083

APPLICANT FILED

: Ute HEIM, et al.,

FOR : May 3, 2001

Cassette for Expression of Arbitrary Genes in

Plant Seed

RESPONSE to RESTRICTION

16 January 2004

Response to Restriction and Amendment to claims.

Respectfully submitted.

Theodore Gottleb, PhD Registration Number 42,597

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED CENTRAL FAX CENTER

JAN 1 6 2004

App. Ser. Nr. : 09/582719

Applicant(s)

: Ute HEIM et al.,

Filing Date

: 3 May 2001

Art Unit

: 1638

Examiner

: Cynthia E. Collins

Title

: New Expression Cassette for Expression of Arbitrary

Genes in Plant Seeds

Commissioner of Patents PO BOX 1450 Alexandria, VA 22313-1450

16 January 2003

SUPPLEMENTAL RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This communication is in response to the office action of 5 January 2004.

Entry of any amendments and consideration of the remarks is respectfully requested.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

ADDITIONAL FEES

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

REMARKS

Claims 1-20 were pending in the application. Claims 14-18 are canceled as described below. <u>Further, claims 21-23 have been added</u>. Claim 23 reads on Group I, will be treated as if it were included in the restriction requirement of 18 July 2003. No new matter has been added.

In sum, the claims are in the condition that Applicants desired upon filing the preliminary amendment of 6 July 2001. A copy of the preliminary amendment was faxed to Examiner on 2 September 2003. Thus, it is understood by Applicants that claims 1-13 and 19-23 are pending in the application.

In addition, replacement specification pages 1 and 2, in clean and mark-up form are attached with an amendment directing the substitution.

Election With Traverse of the Restriction Requirement

In response to the restriction requirement, applicants provisionally elect with traverse, GROUP I comprising claims 1-8, 12-13, and 23.

Comments Supporting Traversal of the Restriction Requirement

Basis for the Alleged Lack of Unity of Invention

The entire basis for issuing the restriction requirement was predicated on the fact that the SBP promoter is considered by Examiner to be the special technical feature required satisfy the unity of invention standard. PCT 13.2. Further, to qualify as an actual technical feature the SBP must define a contribution over the art.

It is then alleged that Heim et al., or Grimes et al., either anticipate or render obvious the claims because they disclose a promoter from a gene encoding a seed protein similar to sucrose binding protein, SBP. Accordingly, the claims are alleged to not define a contribution over the art, thus, rendering the restriction requirement proper.

Response to Examiner's Arguments

In response, it is respectfully pointed out that neither Heim nor Grimes anticipate the claims. Neither do they individually or in combination render the claims obvious.

Heim discloses the sequence of a cDNA to sucrose phosphate synthase. A cDNA clone comprises the coding sequences of a gene and/or the mRNA transcribed from the gene. No promoter sequences are disclosed in the cDNA, as in general, promoters are not themselves transcribed. Therefore, Heim cannot anticipate or render the claims obvious.

In addition, sucrose phosphate synthase is a completely different protein than SBP.

Therefore, Heim cannot anticipate the claims nor cannot it support a presumption of obviousness over completely unrelated sequences.

Similarly, Grimes only provides the coding sequence (cDNA) of a sucrose-binding protein from soybean. There is no disclosure of a promoter sequence in the article. In addition, Grimes uses soybean, which is in the genus *Glycine* (specifically *Glycine max*). This is not identical or even substantially related to the *Vicia faba*.

In sum, the SBP promoter as disclosed and claimed herein clearly defines a contribution over Heim and Grimes. The references, either individually or in combination, do not remotely approximate the SBP promoter sequence.

Accordingly, withdrawal of the restriction requirement is proper, and earnestly requested.

Respectfully Submitted,

Norris, McLaughlin & Marcus 220 East 42 nd Street New York, NY 10017 Telephone (212) 808-0700 Facsimile (212) 808-9844

Theodore Gottlieb,PhD Reg. No. 42, 597 Certificate of Transmission

I hereby certify that this correspondence is being transmitted by facsimile to the U.S. Patent and Trademark Office (Fax No. (703) 872-9306.

on 16-Jan-2004, by

(Date)

Typed or printed name of transmittor

Signature / /

an-18-04 04:57pm From-Norris McLaughlin & Marcus

+212 808 0844

T-689 P.006/013 F-60

Atty Docket: 101195-48

IN THE SPECIFICATION

Substitute current pages 1 and 2 of record, with the attached replacement pages 1 and 2.

New expression cassette for expression of arbitrary genes in plant seeds

BACKGROUND OF THE INVENTION

The invention in question relates to an expression cassette for expression of arbitrary genes in plant seeds and the plasmids containing the expression cassette. The invention also includes the production of transgenic plant cells containing this expression cassette as well as the use of the plasmids in this expression cassette for production of transgenic plants. Fields of application of the invention are biotechnology, pharmacy and plant production.

For a long time now, there have been methods making it possible to integrate relevant genes into the genome of higher plants. The objective of this work is the production of plants with new properties, for example to increase agricultural production, to optimise manufacture of foodstuffs and to produce specific pharmaceuticals and other interesting ingredients. One prerequisite for the expression of the transferred genes in this context is that they possess plant-specific promoter sequences. For this purpose, so-called constitutive promoters such as the promoter of the nopaline synthase gene /1/, the TR double promoter /2/ or the promoter of the 35S transcript of the cauliflower mosaic virus /3/ are used. One disadvantage of these promoters is that they are active in almost all the tissues of the manipulated plants. In this way, a controlled and purposeful expression of the foreign genes in the plants is not possible. It is better to use promoters which function tissue-specifically and independently of development. Genes with the matching promoters, which are only active in anthera, ovaries, blooms, leaves, deciduous leaves, stems, roots or seeds, have been isolated /4/. But they differ greatly in the strength and specificity of the expression and only have a limited use. For the use of the seeds as a source of nutrition and for production of ingredients, it is above all the seed-specific promoters which 2

are of great interest. With the years of research into the genes of the seed-storage proteins, some more or less specific promoters with differing strengths, for example that of phaseolin /5/ or legumin and USP /6/ are available. As these storage proteins are synthesised by gene families, fusions of such promoters with foreign genes are in competition with the endogenous numerous genes of the corresponding gene family. For this reason, it is more favourable to use promoters from unique, strongly and specifically expressing genes. For coand multiple transformations, the use of differing regulatory sequences is suitable, in order to make better use of the development of the seed in time, to synthesise identical or differing gene products in parallel and to avoid cosuppression.

Although a number of expression cassettes for expression of arbitrary genes in plant seeds are already known, the expression rates in plant seeds achieved have not been optimal up to now for the substantiation of a plant biotechnological production of the required materials.

SUMMARY OF INVENTION

The invention therefore has the objective of placing the seed-specific expression in transgenic plants on a basis suitable for a production of materials. It is based on the task of constructing an expression cassette with which a stable expression with a high expression rate of genes of the materials to be produced can be achieved in plant seeds.

The objective of the invention is achieved with the expression cassette described in claim 1, with sub-claims 2-7 being preferred variants.

BRIEF DESCRIPTION OF THE DRAWINGS

The expression cassette according to the invention contains the following essential component parts:

 the promoter of the gene of the sucrose binding protein (SBP) like protein New expression cassette for expression of arbitrary genes in plant seeds

Description

The invention in question relates to an expression cassette for expression of arbitrary genes in plant seeds and the plasmids containing the expression cassette. The invention also includes the production of transgenic plant cells containing this expression cassette as well as the use of the plasmids in this expression cassette for production of transgenic plants. Fields of application of the invention are biotechnology, pharmacy and plant production.

For a long time now, there have been methods making it possible to integrate relevant genes into the genome of higher plants. The objective of this work is the production of plants with new properties, for example to increase agricultural production, to optimise manufacture of foodstuffs and to produce specific pharmaceuticals and other interesting ingredients. One prerequisite for the expression of the transferred genes in this context is that they possess plant-specific promoter sequences. For this purpose, so-called consticutive promoters such as the promoter of the nopaline synthase gene /1/, the TR double promoter /2/ or the promoter of the 35\$ transcript of the cauliflower mosaic virus /3/ are used. One disadvantage of these promoters is that they are active in almost all the tissues of the manipulated plants. In this way, a controlled and purposeful expression of the foreign genes in the plants is not possible. It is better to use promoters which function tissue-specifically and independently of development. Genes with the matching promoters, which are only active in anthera, ovaries, blooms, leaves, deciduous leaves, stems, roots or seeds, have been isolated /4/. But they differ greatly in the strength and specificity of the expression and only have a limited use. For the use of the seeds as a source of nutrition and for production of in2

gredients, it is above all the seed-specific promoters which are of great interest. With the years of research into the genes of the seed-storage proteins, some more or less specific promoters with differing strengths, for example that of phaseolin /5/ or legumin and USP /6/ are available. As these storage proteins are synthesised by gene families, fusions of such promoters with foreign genes are in competition with the endogenous numerous genes of the corresponding gene family. For this reason, it is more favourable to use promoters from unique, strongly and specifically expressing genes. For coand multiple transformations, the use of differing regulatory sequences is suitable, in order to make better use of the development of the seed in time, to synthesise identical or differing gene products in parallel and to avoid cosuppression.

Although a number of expression cassettes for expression of arbitrary genes in plant seeds are already known, the expression rates in plant seeds achieved have not been optimal up to now for the substantiation of a plant biotechnological production of the required materials.

The invention therefore has the objective of placing the seed-specific expression in transgenic plants on a basis suitable for a production of materials. It is based on the task of constructing an expression cassette with which a stable expression with a high expression rate of genes of the materials to be produced can be achieved in plant seeds.

The objective of the invention is achieved with the expression cassette described in claim 1, with sub-claims 2-7 being preferred variants.

The expression cassette according to the invention contains the following essential component parts:

· the promoter of the gene of the sucrose binding protein (SBP) like protein